Environmental Protection Agency
[FRL-]
Technical Workshop on Perchlorate Risk Issues

AGENCY: U.S. Environmental Protection Agency (EPA)
ACTION: Notice of Meeting

SUMMARY: EPA is announcing a workshop convened by the Research Triangle Institute (RTI), an EPA contractor, for external scientific peer review of the EPA draft document entitled "Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization Based on Emerging Information." The workshop will be held in San Bernardino, California, and will be open to members of the public as observers. The peer review, to be conducted by scientists from outside EPA, is being organized to assist in completing the toxicological review and risk characterization of perchlorate, and will include the protocols and reports of recent studies on perchlorate, as well as EPA's draft Toxicological Review document. Stakeholders in the perchlorate issue who have additional information which is relevant to the assessment of the potential health and ecological effects of perchlorate are invited to make a short presentation of this information at the peer review workshop.

DATES: The workshop will begin on Wednesday, February 10, 1999 at 8:30 a.m. and end on Thursday, February 11, 1999 at 12:30 p.m. Members of the public may attend as observers.

ADDRESSES: The meeting will be held at the San Bernardino City Council Chambers, 300 North D Street, San Bernardino, California 92418. Since seating capacity is limited, please contact Ella Darden of RTI, by telephone, at 919-541-7026; by facsimile, at 919-541-7155; or by E-mail, at ejd@rti.org, by January 31, 1999 to attend the workshop as an observer. Observers who wish to make a short presentation of information which may be relevant to the assessment of potential health and ecological effects of perchlorate should register to do so with RTI by January 31, 1999.

FOR FURTHER INFORMATION CONTACT: For technical and logistical inquires, contact Ella Darden, Research Triangle Institute, by telephone, at 919-541-7026; by facsimile, at 919-541-7155; or by E-mail, at ejd@rti.org. Copies of the draft Toxicological Review document will be available for inspection on EPA's National Center for Environmental Assessment web site (http://www.epa.gov/ncea/perch.htm), at EPA's Regional Superfund Records Centers, and at the EPA Headquarters Information Resources Center, Washington DC. Inquiries concerning additional opportunities for document review should be directed to Ella Darden at Research Triangle Institute.

SUPPLEMENTARY INFORMATION:

Background

EPA is in the process of conducting a toxicological review for perchlorate, including the development of a revised provisional reference dose (RfD), a cancer assessment, and an ecological assessment. An RfD is an estimate of a daily oral human exposure that will result in no deleterious noncancer effects over a lifetime. Ideally, an RfD is based on an array of endpoints that address potential toxicity during various critical life stages, from developing fetus through adult and reproductive stages. The noncancer, cancer and ecological assessments may be used to support development of a health advisory and/or drinking water regulations and cleanup decisions at hazardous waste sites. In accordance with EPA's 1998 Peer Review Handbook, a key step in the development of the Toxicological Review document for perchlorate is the upcoming external peer review, in the form of a workshop, which will cover protocols for and reports of the recently completed toxicity studies, the Toxicological Review document, and the proposed revised provisional RfD, cancer assessment and ecological assessment in that document.

EPA's Superfund Technical Support Center issued a provisional RfD for perchlorate in 1992 and a revised provisional RfD in 1995. The provisional RfD values (1992 and 1995) were based on an acute study in which single doses of potassium perchlorate caused the release of iodide from the thyroids of patients with Graves' Disease. The provisional RfD values did not undergo internal Agency, or external, peer review. In March of 1997 a peer review panel convened by an independent organization, Toxicology Excellence for Risk Assessment (TERA), determined that the health effects and toxicity data for perchlorate were insufficient to generate a credible RfD for risk assessment purposes. The reviewers were concerned that developmental toxicity, notably neurological development due to hypothyroidism during pregnancy, could be a critical health effect of perchlorate that has not been adequately examined in studies to date. They also concluded that insufficient data were available on potential effects of perchlorate on organs and tissues other than the thyroid.

New Health Effects / Toxicology Studies Underway

As a result of that peer review, a set of toxicological and ecological studies was undertaken is underway to address key data gaps and provide a comprehensive database related to the toxicity of perchlorate. The studies are being funded and overseen by a variety of organizations with potential responsibility for perchlorate contamination in the environment including the United States Air Force, the National Aeronautics and Space Administration and the Perchlorate Study Group (PSG).[1]

To date, a 90-day subchronic oral study, a neurobehavioral developmental toxicity study,

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[1]The PSG is a consortium of defense contractors and manufacturers including: Aerojet, Alliant Techsystems, American Pacific/Western Electrochemical Company, Atlantic Research Corporation, Kerr-McGee Chemical Corp. Lockheed Martin, Thiokol Propulsion Group, and United Technologies Chemical Systems.

genotoxicity studies, a segment II developmental toxicity study, and ecotoxicity studies in Daphnia, earthworms, lettuce and fathead minnow have been completed. Currently ongoing studies include a two-generation reproductive toxicity study, absorption, distribution, metabolism, and elimination (ADME) studies, perchlorate mechanistic studies, and immunotoxicity studies. The results of most of these studies will be discussed in the Toxicological Review document and utilized for development of the proposed revised RfD, and cancer and ecological assessment for perchlorate.

Ten independent scientists from the fields of general toxicology, thyroid function and toxicology, developmental toxicology, neurotoxicology, immunotoxicology, pharmacology, genetic toxicology, medical endocrinology with an emphasis on thyroid function, biostatistics, assessment of risks due to non-cancer and cancer health effects, and assessment of risks due to ecological effects will review the scientific data, methods, and analyses, along with the assumptions and uncertainties that are associated with the revised provisional RfD, cancer assessment, and ecological assessment for perchlorate. These scientists were selected by RTI from among the experts nominated by stakeholders for possible service as external peer reviewers. Following the peer review workshop, RTI will issue a report summarizing the workshop. EPA will address the comments of the peer reviewers in finalizing the Toxicological Review document for perchlorate and adopting the revised perchlorate RfD. The RfD will be utilized in performing risk assessments of perchlorate contamination in the environment. Although such risk assessments will be one of the factors considered in making future decisions regarding perchlorate contamination, these decisions and other risk management issues will not be a part of the peer review process.

Date

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